

Written Testimony

**Felice J. Levine, PhD
American Sociological Association**

**On behalf of the
Consortium of Social Science Associations
in Cooperation with the American Sociological Association**

Submitted to

**The Committee on Assessing the System for Protecting
Human Research Subjects**

**The Institute of Medicine
The National Academies**

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Dr. Federman and Members of the Committee:

Thank you very much for the opportunity to submit comments on the draft accreditation standards regarding the protection of human participants in research. As Executive Officer of the American Sociological Association and as a member of the Executive Committee of the Consortium of Social Science Associations (COSSA), I am pleased to be able to do so on behalf of COSSA. COSSA is an advocacy organization for the social and behavioral sciences, supported by over 105 professional associations, scientific societies, universities, and research institutes.

COSSA appreciates the opportunity to talk about some of the issues and challenges for the social and behavioral sciences under the proposed standards of accreditation for the protection of human subjects in research. COSSA believes in promoting sound science with sound ethical practices. Most of our professional associations have developed ethical guidelines for researchers to follow in conducting their studies, particularly where human subjects are part of the research design. All embrace the Belmont Report's admonitions of respect for persons, beneficence, and justice. We are, however, concerned with the growing fault lines in the system that protects human subjects and by the gap that has developed between law and policy on-the-books and in-action. For example, researchers utilizing secondary data are being asked to seek approval by IRBs to use these data where the information is in anonymous form and where subjects are already protected under earlier protocols. We hope the Committee will examine such issues closely, not only in assessing these draft standards, but also in your larger study of the whole system of protecting human research participants.

For the social and behavioral sciences, the overall problem with the system is the attempt to fit our research into a framework that was overspecified and designed for biomedical-clinical research. The presence of IRBs in academic and other research organizations dates back to 1974 when federal guidelines were established for the protection of human subjects. While social and behavioral science research was included from the outset, much of the impetus for such guidelines grew out of concerns about informed consent and risks involved in biomedical research. Despite the passage of time, this model of science continues to color the operations of the system, the understanding of best ethical practices, and the functioning of Institutional Review Boards (IRBs).

The proposed standards that we are here to discuss today provide further evidence of this inherent problem. If these standards are intended to be universal and fit all research involving human participants, then they need to be framed in a way that meaningfully includes all research fields. Standing alone, for example, the very long mention at the beginning of Section 3 of Henry Beecher and his 1966 article on "Ethics and Clinical Research" focuses too

exclusively on physicians and on "performing experiments" on humans. This type of preamble sends the wrong signal. We need to take this opportunity to send inclusive signals about a broader band of research involving humans.

Before offering our specific observations of the draft accreditation standards, we address some general concerns about the standards and about the system for protecting human research subjects. We have framed our observations as a series of ten recommendations. Most are broadly applicable to accreditation and the overall system; some deal with issues that are particularly important for improving the ethical consideration of research in the social and behavioral sciences. We believe that these recommendations could and should usefully guide the IOM Committee in both the assessment of the system and the development of accreditation standards.

GENERAL RECOMMENDATIONS

1) Seize the Moment for Effective Leadership on Behalf of All Science. IOM has the opportunity to provide guidance on an accreditation system and a human research participant protection system that effectively reaches to all areas of scientific research and effectively serves all Federal funding agencies engaged in the support of such research—not just the biomedical sciences. The social and behavioral sciences have been committed to this system and its objectives, but often, in practice, the ethical requirements of our sciences have not been consistently and effectively understood.

2) There is Virtue to Moving Ahead, but There is Also Virtue to Slowing the "Train" Sufficiently to Ensure We Can Turn a New Corner. If the standards for accreditation are to be more effective than the current process for obtaining assurances of compliance under the Common Rule, then the two important IOM studies yet to be undertaken should logically proceed before the final crafting and finalizing of accreditation standards. Simply put, perhaps the final accreditation standards should follow after studies two and three and not before.

3) Where's the Fit? The proposed accreditation standards integrate many pieces of the Common Rule but use these regulations in a different context and often coupled with other ideas. Accreditation standards should accredit to the regulations in place; the goal of accreditation is to ensure that the regulations are followed, not to produce additional regulations. The disjuncture between the Common Rule and the accreditation standards needs careful analysis. It may be wisest to have accreditation standards that ensure the effective implementation of the Common Rule guidelines. Then, perhaps as part of introducing accreditation standards, an evaluation could be undertaken to assess whether the system is working effectively and what gaps exist. The problem in the past has been less the actual rules governing the human research protection system than implementation of them.

4) The Devil is in the Details. The proposed accreditation standards are not *per se* couched in the language of any one science or arena of research, but, when coupled with the Commentary, these standards are quite biomedical and heavily clinical and pay only lip service to other substantive arenas of work. This is especially problematic for the social and behavioral sciences. Will the Commentary be presented? If so, the role of the Commentary needs to be clear, and the examples across areas of research need to be specified.

5) While Good Ethics Makes for Good Research, Judgments of Best Ethical Practices are Distinct from Judgments about the Quality of the Research. The proposed accreditation standards overreach to what constitutes quality science and do not sufficiently distinguish between those judgments and what constitutes ethical practices in science. Standards shift from the criteria for the accreditation of IRBs to the assessment of the research and the researcher. The standards need to emphasize accrediting the structure put in place and the procedures to be followed for the protection of human participants in research.

6) Clarity, Simplicity, and Transparency are Fundamental to Accreditation Standards of Excellence. Many of the standards require judgments that are impossible to make. The standards should not tell an institution how it should achieve its goals, but should set forth what the standards or goals are. The standards should focus on the actual facts of what is required and not engage in standard setting or determinations that are highly subjective or elusive. The Commentary is often so detailed that, by omission, it is limiting in its scope; at other points, the standards are so vague as to be subject to widely different interpretations. Ironically, the movement to accreditation in large part aims to transcend such problems—with the promulgation of reproducible standards intended to be the backbone.

7) The Educative Role of Accreditation Standards Can be More Powerful than its Regulatory or Enforcement Functions. We know from research on compliance and non-compliance, that the primary power of a rule system is in its moral persuasion and educative effects. Yet, the proposed accreditation standards, especially the Commentary, provide little education for IRBs regarding how the human research protection system should operate—especially for the social and behavioral sciences.

8) Less Can be More: Accreditation Standards Should Ensure that the Human Research Protection System Does Not Overreach Its Role and that it Stays on Task. The human research protection system needs to ensure that research proceeds and knowledge is advanced in accordance with the highest standards of ethical practice with respect to human subjects protection. The system needs also to ensure that work that comports to ethical standards is facilitated and not impeded by the process. For example, research involves risk at various levels—standards should hold IRBs to the task of effectively implementing what was intended to be exempt or expedited and what requires

full review. Consent is another area where IRBs need to have knowledge about how to undertake research ethically. Studies of runaway youth, for example, raise different issues about parental consent than do observational studies of preschoolers in a classroom.

9) Human Research Participants Refer to Actual Participation in a Study Underway or Being Proposed. The accreditation standards need to make clear to IRBs what the scope of the human research protection system is and is not. The analysis, for example, of public use data or public use files where information is maintained in anonymous form and without personal identifiers is research *about* people but not *on* people. The definition of human subjects under the Common Rule defines the scope of its purview as research on living individuals when an investigator obtains data through an intervention or interaction or obtains identifiable private information. For a human research protection system to focus on this domain and to do it well—with appropriate attention to level of risk—is to achieve an important goal.

10) Focus on the Ethical Considerations regarding Human Research Participants in Various Types of Research. The answer to concerns in the social and behavioral sciences is not to create a dual human research protection system but to ensure a system that is more sophisticated about ethical practices across fields of science. Social and behavioral science research is increasingly interdisciplinary within fields and across especially biomedical, environmental, public health, and engineering fields. Separation of the review by field could create redundancy and limit researchers mutually benefiting from the ethical expertise of each other. But, this puts a burden on ensuring that an altered human research protection system includes the necessary and appropriate expertise on ethical practices in the social and behavioral sciences. The composition of IRBs is very important; other parts of the system also need to be savvy about ethical practices in the social and behavioral sciences.

SPECIFIC ILLUSTRATIVE CONCERNS

Our general recommendations raise questions that speak to the overall thrust, tone, scope, and reach—if not overreaching—of the accreditation standards as currently crafted. They also speak to how and when the IOM might be best situated to develop and recommend accreditation standards for Institutional Review Boards. Because our general concerns speak to each of the standards, we offer below some illustration of the type of revisions and development work that would be required in any revision process.

Section on Principles Underlying should be expanded to set the tone of what is meant to be included within the scope of the Belmont Report and the Common Rule (45 CFR Part 26). Note, for example, the reference in paragraph two to only "experimental subjects." This should be changed to "who agree to be research participants (subjects)" or similar language.

Definitions should explicitly include "colleges and universities" not just "universities."

Proposed Standard 1.7 calls for the review of the policies and procedures of the Human Research Protection Plan. We suggest that it include a clause that periodic review must include input from the scientific community and researchers as to whether the policies and procedures are effectively protecting research participants and enabling the progress of research.

Proposed Standard 1.9 would benefit from explicit recognition of the social and behavioral sciences. The language and Commentary of 1.9 should be appropriately amended. Such a modification would make clear that the social and behavioral sciences are different from the biomedical/clinical sciences and that, in a meaningful protection of research participants, ethical principles need to be applied and implemented appropriate to the substance and methodologies of the work. We urge that the Human Research Protection Plan recognize that research in the social and behavioral sciences often involves different situations (from clinical experiments) regarding the protection of human subjects. The Plan could allow for specialty IRBs or certainly IRBs with appropriate expertise in the social and behavioral sciences and ethical practices therein.

Proposed Standard 1.11 should make clear that expertise for the chair needs to include expertise regarding ethical issues as they pertain to human participants in social and behavioral science research. Language could be added to the effect of "across all fields of science germane to the work of the IRB." As in the Commentary, perhaps the proposed standard should refer to both the chair and the members. The Commentary can make clear that every chair cannot be expert in the specifics of all arenas of inquiry, but that chairs need to display a breadth of interest and exposure that signals knowledge and openness across fields. Also, the reference to "organization culture" seems superfluous to an accreditation standard. It is not clear how one would measure "their [IRB chairs] contribution to the organization's culture." It is also unclear why this determination is included in the Commentary and the fit between this language and requirements for assurances under the Common Rule.

Proposed Standard 1.14 focuses on the performance of an organization's HRPP—emphasizing the importance of assessment and evaluation. The Commentary, however, should refer only to the HRPP overall and the IRBs, not to the investigator. The evaluation, of course, focuses on whether the HRPP is effectively performing its functions of protecting human participants in research and thus necessarily examines how the system identifies and deals with problems. The Commentary, however, should not imply that there is a further assessment of the performance of investigators beyond examining how the system operates with respect to the ethical monitoring of investigations. Also, the Commentary should not explicitly cite any group like PRIM&R and what roles

it might perform because such roles are not mandated by the accreditation process. Also, the Commentary should allow for successful assessments and how they will be duly recorded and reported.

Proposed Standard 1.15 does not recognize the breadth and nature of communities of research when it charges this function to the "organization." As currently written, the proposed standard seems also to confuse an implied "local" community with populations at risk and groups requiring special sensitivity because of their vulnerabilities. If it is to be retained as a standard, it needs to be clear how community is defined. Does it include international communities in multi-national research? Unlike in clinical trials where the subject population might be drawn from the proximal community, in the social and behavioral sciences, the sites for research and the locations of relevant research participants and research communities can be geographically wide ranging. Typically samples are drawn not based on geographic convenience to the investigator, but on the substantive ideas motivating the research. Researchers need to demonstrate sensitivity to relevant research communities, but it is unclear how or why the "organization" would be charged with doing so. Therefore, as an accreditation standard for HRPP, this should be deleted.

Proposed Standard 2.3 has examples in the Commentary that could usefully be broadened. The Commentary should also use explicit language that signals the social and behavioral sciences. Here and throughout "i.e." is used when it seems that "e.g." is meant.

Proposed Standard 2.4 seems to focus on traits beyond substantive expertise in relevant ethical areas embraced by the IRB. Why is this section necessary as an accreditation standard, how does it link to the assurances specified in the Common Rule, and what does it add beyond Proposed Standard 1.11? Especially in the Commentary, it reads far too much like a job description. The accreditation standards need to focus on required structures and processes; it seems unnecessary and unwise to frame the standards in terms of personality attributes of those who serve. The Standard itself talks about "sufficient respect" and other elusive traits which we believe are far too subjective and not very useful. Therefore, we recommend that this whole section should be eliminated.

Proposed Standard 2.5 and the Commentary could usefully signal the breadth of research involving human subjects. The text should read: The IRB administrator, staff, chair(s), and Board members must possess and maintain knowledge, skills and abilities appropriate to the actual conduct of research across all areas of study with human subjects. IRB chairs and members should be encouraged to attend scientific society meetings and their ethics workshops so that they understand the ethical requirements put on the researcher by his/her professional community. Language in Commentary should not explicitly privilege—even by example—any one certification process like CCIP. Standards should be neutral on their face and should not promote any specific programs.

Proposed Standards 2.8 and 2.9 should be in reverse order. The appropriateness of the consent process should take precedence over the legibility of the consent documents.

Proposed Standard 2.10 needs clarification. The Commentary is misguided. The IRB should not be determining who should serve as principal investigator and whether that person is qualified to lead a research project. That should be left to peer review of the substance of the research itself. The IRBs' attention should be directed to the processes and procedures to be followed for the protection of human research participants. The language could usefully be modified from "to be responsible for the research" to "to be responsible for the protection of human subjects involved in the conduct of the research." This standard is a further location where the breadth of the fields could be signaled and the social and behavioral sciences more explicitly included.

Proposed Standard 2.11 and specifically its opening Commentary should include a wide array of examples that go beyond health and visibly include examples from the social and behavioral sciences on health and other issues. For example, written specific guidelines for IRBs would be useful in the area of survey research (including with respect to different populations), and IRBs would benefit from being better informed (and having greater expertise) regarding how risk or adverse circumstances may be different in survey research. As elsewhere, the current examples (after the "i.e.," are essentially all clinical or biomedical.)

Proposed Standard 2.11 (E) (F) essentially has no Commentary. This is an area where the accreditation standards can ensure that the HRPP system and the operations of IRBs reach—not overreach—to what is meant to be included. The specification of Commentary here could usefully educate IRBs about human subjects protection with respect to a considerable amount of work in the social and behavioral sciences. Research qualified for exemption or expedited review needs to be explicitly stipulated and reference made to the Common Rule.

Proposed Standard 2.12 and 2.13 could usefully be aligned with the Common Rule; in their present form, they are too prescriptive. They should be simplified so that the goals and purposes of the IRB record keeping are clear and so that someone not party to the process or the meeting could be expected to understand what has happened and why.

Proposed Standard 3, as noted above, needs to have the General Commentary recast to explicit capture all fields of research, not just the biomedical and clinical fields. In Commentary about investigators, *all* researchers and *all* IRBs need to see that these accreditation standards includes social and behavioral science research and other germane fields.

Proposed Standard 3.4 needs to explicitly account for exempt research and the alignment between the responsibility of the IRBs and the investigators. Also, the Commentary gives final authority to the IRBs. We recommend that the IRB should not have the sole authority in the organization to determine what constitutes protection of human participants in research. There should be some avenue of appeal of IRB decisions. Thus, if an IRB determined that a given project, such as secondary analysis of data, should not be exempt, there needs to be another body where the researcher can make his/her case and which is charged with determining if the IRB operated consistent with regulations.

Proposed Standard 3.5 substantially overlaps Standard 2.10, which, as noted earlier, needs clarification. The one difference is the emphasis on "delegation." Were this Standard to be retained, it should read: "Principal Investigators (PIs) may delegate responsibility for aspects of human subjects protection only to individuals who are qualified through training and experience for this role."

Proposed Standard 3.7 is vague and unclear as to its purpose and intent. It sounds almost like a "litmus test" that goes well beyond the high level of ethical practices that an investigator may set for his or her own research. Furthermore, it is unclear how it would be measured. We recommend that it be eliminated.

CONCLUSION

In addressing both our general recommendations and specific concerns, we in the social and behavioral sciences and in the scientific societies can be very useful. We stand ready to do so under the auspices of COSSA. Other key agencies outside of the health sciences that fund and support research with human participants can also help to bring appropriate knowledge to bear. The National Science Foundation is key in that regard. We believe that such guidance can help structure the next round of revisions for a final set of "testable" accreditation standards. We at COSSA as well as many, many top quality researchers behind us are eager to help in any way we can.

Thank you for the opportunity to present our views.